DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Stanley Slavin, President
M. Slavin & Sons, Ltd.
31 Belmont Avenue
Brooklyn, NY 11212

August 21, 2001

Ref: NYK-2001-115

Dear Mr. Slavin:

We inspected your seafood processing facility, located at 106 South Street in New York, New York, on July 16 through 19, 2001 and found that you have serious deviations from the Seafood HACCP regulations (Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123)). These deviations, some of which were previously brought to your attention, cause your scombrotoxin (histamine) forming species of fish (e.g., tuna, mahi mahi, and mackerel), vacuum packaged raw salmon, and refrigerated pasteurized canned crabmeat to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the Seafood HACCP regulations through the links in FDA's home page at www.fda.gov.

The deviations included, but are not limited to, the following:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm did not have a HACCP plan for the receipt, outdoor display, and storage of vacuum packaged raw salmon to control the food safety hazard of *Clostridium botulinum* toxin formation. Further, your firm did not have a HACCP plan for the receipt, outdoor display, and storage of refrigerated pasteurized canned crabmeat to control the food safety hazard of *Clostridium botulinum* toxin formation.

2. You must implement the monitoring procedures and record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b) and 123.6(c)(7). However, your firm did not follow monitoring procedures and record monitoring observations at the receiving critical control point to control the histamine hazard listed in your HACCP plan for histamine forming species of fish. For example, there was no record that histamine forming species of fish were checked for adequacy of ice and/or internal temperature upon receipt. Further, there was no record that histamine forming fish

were checked for adequacy of ice and/or internal temperature during outdoor display. During the inspection, the investigator observed that king mackerel on outdoor display had an internal temperature as high as 56.6° F and tuna on outdoor display had an internal temperature as high as 52.0° F.

We may take further action if you do not promptly correct these deviations. For instance, we may take further action to seize your products and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please respond in writing within three weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter and the inspectional observations (Form FDA 483) issued to and discussed with Robert D. Katlowitz, Manager at the conclusion of the inspection may not list all the deviations at your facility. You are responsible for ensuring that your seafood processing facility operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Bruce A. Goldwitz, Compliance Officer, 158-15 Liberty Avenue, Jamaica, NY 11433. If you have questions regarding any issue in this letter, please contact Mr. Goldwitz at (718) 340-7000 ext. 5582.

Sincerely,

Robert L. Hart
Acting District Director

Enclosure: Form FDA 483 dated July 19, 2001

cc: Herbert Slavin, Secretary/Treasurer
M. Slavin & Sons, Ltd.
106 South Street
New York, NY 10038